

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MARIA MENDEZ,	:	
	:	
Plaintiff,	:	Civil Action No. 13-1585
	:	(NLH/JS)
RAHUL V. SHAH, M.D., et al.,	:	<u>OPINION</u>
	:	
Defendants.	:	
	:	
	:	

Appearances:

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HILLMAN, District Judge:

Before the Court is Defendants Rahul V. Shah M.D. and Premier Orthopedic Associates Surgical Center LLC's motion for summary judgment as to three claims in Plaintiff Maria Mendez's third amended complaint. For the reasons stated below, the

motion will be granted.

I. BACKGROUND

Plaintiff Maria Mendez suffered from chronic back pain and sought treatment from Defendant Rahul V. Shah, M.D. Dr. Shah diagnosed Plaintiff with spinal stenosis and spondylolistheses and recommended spinal surgery.¹ Dr. Shah first performed surgery on Plaintiff's back on March 21, 2011 and implanted Medtronic brand devices in her spine which Plaintiff alleges failed and caused her injury. These devices include the "Infuse Bone Graft/LT-Cage Lumbar Fusion" device as well as "the Capstone Spinal System, Infuse Bone Graft, MasterGraft Matrix, CD Horizon Legacy screws, [and] Cancellous chips[.]" (Third Am. Compl. ¶ 20 [Doc. No. 131].) Plaintiff states that the Capstone cages and Infuse bone graft were inserted into the spaces between her fourth and fifth lumbar vertebrae (L4/L5) and between the fifth lumbar vertebra and the sacrum (L5/S1). (Pl.'s Counterstatement of Facts ¶ 12 [Doc. No. 182-1].)

Due to increasing pain over several weeks following her March 21, 2011 operation, films were taken of Plaintiff's back which showed the cages had migrated and the L5/S1 hardware failed. Dr. Shah performed a revision surgery on May 18, 2011

¹ The background of this case is set out in further detail in Mendez v. Shah, 28 F. Supp. 3d 282 (D.N.J. 2014).

to remove and replace the L5/S1 spacers.

Plaintiff alleges she sustained "drop foot" and other complications as a result these surgeries. She further alleges that she is disabled and suffers excruciating pain every day. It is not expected that there is any further treatment that could help her.

Originally, Plaintiff brought claims of negligence, medical malpractice, battery, lack of informed consent, breach of the implied warranty of fitness for a particular purpose, breach of express warranty, breach of contract, fraudulent concealment, fraud and misrepresentation, as well as claims pursuant to the New Jersey Product Liability Act ("PLA"). The Court previously dismissed Plaintiff's claims against the medical device manufacturer, Medtronic, primarily based on federal preemption.

(See March 20, 2015 Op. and Order [Doc. Nos. 170, 171].)

Plaintiff voluntarily dismissed Dr. Shah's physician's assistant and the hospital where the surgery was performed. As such, Dr. Shah and Premier Orthopedics are the only remaining Defendants. Defendants do not seek summary judgment on Plaintiff's negligence claims and Plaintiff has withdrawn her breach of warranty and breach of contract claims. Accordingly, the parties dispute only whether Defendants should be granted summary judgment on Counts II (lack of informed

consent/battery), III (New Jersey Product Liability Act), and VII (fraudulent concealment). The parties also dispute whether Plaintiff may claim punitive damages.

II. JURISDICTION

This Court exercises jurisdiction pursuant to 28 U.S.C. § 1332(a), diversity of citizenship. Plaintiff is a citizen of the Commonwealth of Pennsylvania and Defendants are citizens of the State of New Jersey. The amount in controversy exceeds the jurisdictional limit exclusive of interest and costs.

A Court exercising diversity jurisdiction must apply the law of the forum state within which it sits, and therefore, New Jersey law will apply to Plaintiff's state law claims. See Chemical Leaman Tank Lines, Inc. v. Aetna Casualty and Surety Co., 89 F.3d 976, 983 (3d Cir. 1996) (stating that "[a]s a federal court sitting in diversity, we must apply the substantive law of New Jersey.") (citing Borse v. Piece Goods Shop, Inc., 963 F.2d 611, 613 (3d Cir. 1992)).

III. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate where the Court is satisfied that "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a

judgment as a matter of law." Celotex Corp. v. Catrett, 477 U.S. 317, 330 (1986); Fed. R. Civ. P. 56(c).

An issue is "genuine" if it is supported by evidence such that a reasonable jury could return a verdict in the nonmoving party's favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A fact is "material" if, under the governing substantive law, a dispute about the fact might affect the outcome of the suit. Id. In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence "is to be believed and all justifiable inferences are to be drawn in his favor."

Marino v. Industrial Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255). Initially, the moving party has the burden of demonstrating the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once the moving party has met this burden, the nonmoving party must identify, by affidavits or otherwise, specific facts showing that there is a genuine issue for trial. Id. Thus, to withstand a properly supported motion for summary judgment, the nonmoving party must identify specific facts and affirmative evidence that contradict those offered by the moving party. Anderson, 477 U.S. at 256-57. A party

opposing summary judgment must do more than just rest upon mere allegations, general denials, or vague statements. Saldana v. Kmart Corp., 260 F.3d 228, 232 (3d Cir. 2001).

IV. DISCUSSION

A. Count II: Lack of Informed Consent and Battery as to Dr. Shah

Count II of Plaintiff's third amended complaint contains two claims: lack of informed consent and battery. The Court will address these claims separately.

1. Lack of Informed Consent

Informed consent is an action in negligence based upon a doctor's duty to provide appropriate information for the patient to make an informed decision regarding his or her medical treatment. Whitley-Woodford v. Jones, 253 N.J. Super. 7, 10-11, 600 A.2d 946, 947 (App. Div. 1992) (citing Largey v. Rothman, 110 N.J. 204, 540 A.2d 504 (1988)). "For consent to be informed, the patient must know not only of alternatives that the physician recommends, but of medically reasonable alternatives that the physician does not recommend. Otherwise, the physician, by not discussing these alternatives, effectively makes the choice for the patient." Matthies v. Mastromonaco, 160 N.J. 26, 38, 733 A.2d 456, 462 (1999) (citation omitted). "The information a doctor must disclose depends on what a

reasonably prudent patient would deem significant in determining whether to proceed with the proposed procedure." Howard v. Univ. of Med. & Dentistry of New Jersey, 172 N.J. 537, 548, 800 A.2d 73, 79 (2002).

While no expert testimony is required to prove that an undisclosed risk would have been material to the patient's consent, a plaintiff must first submit expert testimony showing that the "risk was one of which the physician should have been aware, and that it was recognized within the medical community." Febus v. Barot, 260 N.J. Super. 322, 327, 616 A.2d 933, 935-36 (App. Div. 1992); see also Calabrese v. Trenton State Coll., 162 N.J. Super. 145, 157, 392 A.2d 600, 606 (App. Div. 1978) aff'd, 82 N.J. 321, 413 A.2d 315 (1980) ("[where] a doctor has been shown to have made disclosure of some of the risks associated with the proposed treatment, the alleged inadequacy of his disclosure must be established by expert medical testimony because no lay jury can be expected to reach a conclusion on such a technical matter unaided by such testimony.").

While Plaintiff does not allege that Dr. Shah failed to inform her of several serious medical risks of her spinal surgery, she contends that Dr. Shah should have informed her of the increased risk of harm of using Medtronic devices. She further alleges that a reasonable patient would not have

consented to the procedure had she been fully informed about the off-label and experimental use of the products. (3rd Am. Compl. ¶¶ 66, 68, 72.) Plaintiff further alleges that Dr. Shah should have informed Plaintiff of his financial arrangement with Medtronic. (*Id.* ¶ 67.)

Plaintiff's informed consent claim fails as a matter of law because she must establish through expert testimony that Dr. Shah's disclosures to her were inadequate. Plaintiff's sole expert report of Dr. Kim Garges is devoid of any testimony concerning any risk Dr. Shah should have disclosed. Thus, summary judgment must be granted Plaintiff's claim of lack of informed consent. *Febus*, 260 N.J. Super. at 328 (affirming district court's order of summary judgment on informed consent claim where plaintiff failed to produce an expert report which stated that the risk not disclosed was recognized by the medical community).

2. Battery

In contrast to a claim of lack of informed consent, battery is an intentional tort whereby a doctor does not obtain the consent of his patient to perform a particular operative procedure. *Whitley-Woodford*, 253 N.J. Super. at 11. Unlike informed consent, expert testimony is not required to prove deviation from a standard of care. *Id.* Battery occurs, for

example, where a doctor implants a cadaver bone into a patient contrary to the patient's specific instructions (Murphy v. Implicito, No. A-3172-03T3, 2005 WL 2447776 (N.J. Super. Ct. App. Div. Sept. 22, 2005)) or when a patient consents to surgery by one surgeon but is operated on by another (Perna v. Pirozzi, 92 N.J. 446, 457 A.2d 431 (1983)).

Here, there is nothing in the record to suggest that Dr. Shah performed a procedure substantially different from the spinal surgeries Plaintiff authorized in the surgical consent forms she signed. Accordingly, summary judgment will be granted on Plaintiff's battery claim, as well.

B. Count III: Liability of Health Care Providers For Medical Devices Under the New Jersey Product Liability Act, N.J. Stat. § 2A:58C-11, as to Dr. Shah and Premier Orthopedic

Under the New Jersey Product Liability Act, a health care provider cannot be held liable for harm allegedly caused by a medical device unless: "(1) the provider has exercised some significant control over the design, manufacture, packaging or labeling of the medical device relative to the alleged defect in the device which caused the injury, death or damage; or (2) the provider knew or should have known of the defect in the medical device which caused the injury, death or damage, or the plaintiff can affirmatively demonstrate that the provider was in possession of facts from which a reasonable person would

conclude that the provider had or should have had knowledge of the alleged defect in the medical device which caused the injury, death or damage; or (3) the provider created the defect in the medical device which caused the injury, death or damage." N.J. Stat. § 2A:58C-11.

This statute codified existing New Jersey common law precedent which opposed the imposition of strict liability on health care providers unless they had control over the design, manufacturing, packaging, or labeling of the product, created the defect, or knew or should have known of the product defect. Seavey v. Globus Med., Inc., No. 11-2240, 2014 WL 1876957, at *18 (D.N.J. Mar. 11, 2014) (citing Johnson v. Mountainside Hosp., 239 N.J. Super. 312, 322-23, 571 A.2d 318 (App. Div. 1990); Feldman v. Lederle Labs., 97 N.J. 429, 442, 479 A.2d 374 (1984); Brody v. Overlook Hosp., 66 N.J. 448, 450, 332 A.2d 596 (1975)).

Here, Plaintiff does not allege that Defendants had any control over the design, manufacture, packaging or labeling of the Medtronic devices. Nor does Plaintiff allege that Defendants caused any defect in the devices. Rather, Plaintiff alleges that Defendants should have known that the way in which Dr. Shah used the Medtronic devices would injure Plaintiff. Defendants argue that Plaintiff has offered no expert testimony

regarding what Dr. Shah should have known regarding the use of Medtronic devices and dispute that they should be held strictly liable under the New Jersey PLA.

The plaintiff in Seavey v. Globus Med., Inc., No. 11-2240, 2014 WL 1876957 (D.N.J. Mar. 11, 2014), similarly complained that a medical device was used in an off-label fashion in his spinal surgery and alleged a products liability claim against his doctor. As the court reasoned in Seavy, "Plaintiff's products liability claim against Dr. Testaiuti constitutes an attempt to shoehorn a medical malpractice or informed consent claim into a products liability cause of action by attempting to characterize off-label use and the risks associated with such use as a 'defect.'" Id. at *19. The court continued:

Plaintiff has cited no law, and the Court is aware of none, suggesting that he can use a products liability claim as a second attempt at a negligence claim against a physician, without having to demonstrate the standard of care. To allow such a cause of action to proceed would be to dispense with the expert testimony requirement for both medical negligence and informed consent claims by allowing an analogous claim to proceed in the guise of a product liability cause of action. Further, the PLA is a strict liability statute. Green v. Gen. Motors Corp., 310 N.J. Super. 507, 517, 709 A.2d 205 (App. Div. 1998). To allow a product liability claim against a surgeon to proceed past summary judgment based on off-label usage would allow litigants to hold physicians strictly liable for harm resulting from any off-label use of a device, which would be in contravention of established New Jersey law. Blazoski v. Cook, 346 N.J. Super. 256,

270-71, 787 A.2d 910 (App. Div. 2002). Summary judgment will thus be granted in favor of the medical provider defendants on this claim.

Id. at *19. The Court agrees with and adopts the analysis of the Seavy court. Plaintiff submitted no expert testimony (or any other evidence) establishing that there was defect in the Medtronic products that Defendants knew of or should have known of which caused Plaintiff's injury. Additionally, the Court will not impose strict liability on Defendants for what is at its core a medical malpractice claim and not a product liability claim. Accordingly, Defendants will be granted summary judgment on Count III.

C. Count VII: Fraudulent Concealment as to Dr. Shah and Premier Orthopedic

The elements that must be established by a plaintiff in a fraudulent concealment action are:

- (1) That defendant in the fraudulent concealment action had a legal obligation to disclose evidence in connection with an existing or pending litigation;
- (2) That the evidence was material to the litigation;
- (3) That plaintiff could not reasonably have obtained access to the evidence from another source;
- (4) That defendant intentionally withheld, altered or destroyed the evidence with purpose to disrupt the litigation;
- (5) That plaintiff was damaged in the underlying action by having to rely on an evidential record that did not contain the evidence defendant concealed.

Rosenblit v. Zimmerman, 166 N.J. 391, 406-07, 766 A.2d 749, 757-58 (2001). In her third amended complaint, Plaintiff alleges

that she has not received requested copies of her medical records and films which are in the possession of Defendants. (Third Am. Compl. ¶¶ 127, 131.) Plaintiff also alleges that records and films from the March 2011 surgery were previously provided by the former hospital defendants on or about June 26, 2015. (Id. ¶ 134). Plaintiff argues in her brief that she has received discovery in "bits and pieces" and that during Dr. Shah's May 16, 2015 deposition she discovered that pictures were taken during the surgeries which were not produced. (Opp. at 24 [Doc. No. 182-1].) Thus, plaintiff alleges the pictures were "intentionally withheld" and that some X-rays "may not have been produced." (Id. at 25.) Defendants argue that the medical records and films were in the custody and possession of the now-dismissed hospital defendants and that nothing has been withheld or concealed.

Plaintiff has submitted no evidence that she could not have reasonably obtained access to the evidence from another source (i.e. the hospital defendants) or that Defendants intentionally withheld, altered or destroyed the evidence with purpose to disrupt the litigation.² See Ellison v. Winteringham Associates,

² Additionally, the Court notes that L. Civ. R. 37.1 requires the parties to meet and confer to resolve discovery disputes before submitting such disputes to the Court.

L.P., No. A-1077-13T2, 2014 WL 8132002, at *7 (N.J. Super. Ct. App. Div. Mar. 17, 2015) (affirming trial court's order for summary judgment on fraudulent concealment claim where there was no showing that defendants intentionally demolished evidence in order to thwart potential litigation); Lawshe v. Squeri, No. 03-3506, 2010 WL 276232, at *11 (D.N.J. Jan. 19, 2010) (granting summary judgment for defendants on fraudulent concealment claims where plaintiffs failed to show "(i) that Defendants had a legal obligation to disclose any evidence that was not produced, (ii) why Plaintiffs could not have obtained the requested evidence from another source, and (iii) that Defendants intentionally withheld, altered or destroyed any evidence to disrupt this litigation."). Accordingly, summary judgment will be granted because Plaintiff has submitted no evidence that the third and fourth elements of a fraudulent concealment claim have been satisfied.

D. Punitive Damages

As the Court has determined that summary judgment is appropriate as to Counts II, III, and VII, the only remaining claim is for negligence. Pursuant to N.J. Stat. Ann. § 2A:15-5.12 ("Punitive Damages"), "[p]unitive damages may be awarded to the plaintiff only if the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of

the defendant's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions. This burden of proof may not be satisfied by proof of any degree of negligence including gross negligence." See also Edwards v. Our Lady of Lourdes Hosp., 217 N.J. Super. 448, 460, 526 A.2d 242, 248 (App. Div. 1987) ("Neither mere negligence nor gross negligence can support an award of punitive damages."); Smith v. Whitaker, 160 N.J. 221, 242 (1999) ("Mere negligence, no matter how gross, will not suffice as a basis for punitive damages."). Accordingly, because Plaintiff's only remaining claim is a claim for negligence, Plaintiff may not demand punitive damages.

V. CONCLUSION

Summary judgment will be granted on Counts II, III, and VII for Defendants. Plaintiff may not seek punitive damages. An appropriate Order will be entered.

s/ Noel L. Hillman
NOEL L. HILLMAN, U.S.D.J.

At Camden, New Jersey

Dated: March 3, 2016